

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

**ALETHA H. PARDUE,**

**Plaintiff,**

**v.**

**GENERAL ELECTRIC COMPANY d/b/a  
GE HEALTHCARE, a New York  
corporation; GE MEDICAL SYSTEMS  
INFORMATION TECHNOLOGIES, INC., a  
Wisconsin corporation; GE HEALTHCARE  
IITS LLC, a Delaware corporation; GE  
HEALTHCARE IITS USA CORP, a Vermont  
corporation,**

**Defendants.**

**COURT FILE NO.: \_\_\_\_\_**

**COMPLAINT**

COMES NOW, Plaintiff in the above-styled action, and files this Complaint against General Electric Company d/b/a GE Healthcare, a New York corporation; GE Medical Systems Information Technologies, Inc., a Wisconsin Corporation; GE Healthcare IITS LLC, a Delaware corporation; and GE Healthcare IITS USA Corp., a Vermont corporation; and, in support thereof, states as follows:

**PARTIES**

1. Aletha H. Pardue, is an individual above the age of nineteen (19) and is a resident of Madison County, Alabama.

2. At all times material hereto, Defendant General Electric Company d/b/a GE Healthcare, was and is a corporation organized, existing, and doing business under and by virtue of the laws of the state of New York, with its global headquarters located in Chalfont St. Giles, Buckinghamshire, United Kingdom.

3. At all times material hereto, Defendant GE Medical Systems Information Technologies, Inc., was and is a Wisconsin corporation with its principal place of business located in Milwaukee, Wisconsin.

4. At all times material hereto, Defendant GE Healthcare IITS, LLC, was and is a primary business unit of GE Healthcare with its business headquarters located in Barrington, Illinois.

5. At all times material hereto, Defendant GE Healthcare IITS USA Corp. was and is a primary business unit of GE Healthcare with its business headquarters located in Burlington, Vermont.

6. All entities identified in paragraphs 2 through 5, above, are collectively referred to as "GE Defendants."

7. Defendants includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns, and their present officers, directors, employees, agents, representatives, and other persons acting on their behalf.

#### **JURISDICTION AND VENUE**

8. Plaintiff repeats and re-alleges paragraphs 1 through 7 as if fully set out herein.

9. Given the amount in controversy and the nature of claims plead *infra*, and given the diversity of citizenship between the parties, this Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a)(1).

10. This Court has personal jurisdiction over Defendants.

11. Venue is proper in this Court with respect to Defendants as per binding Minnesota authority.

**FACTS**  
**Radiation: Its Uses and Effects**

12. Plaintiff repeats and re-alleges paragraphs 1 through 11.

13. The common name for energy emitted from X-ray machines is ionizing radiation. The name indicates that the radiation has sufficient energy to ionize atoms and molecules. Ionization takes place when radiation changes the charge of the atoms or molecules it strikes. As used throughout this Complaint, the term “radiation” means ionizing radiation.

14. Doctors use radiation for diagnostic applications. In fact, one of the main tools available for diagnosis is computer aided tomography (a “CT scan.”) A CT scan is a diagnostic imaging procedure that uses a combination of X-ray radiation and computer technology to produce cross-sectional scans or “slices,” both horizontally and vertically, of the human body.

15. However, CT scans are more detailed than a standard X-ray. In computer tomography, the X-ray beam moves in a circle around the body. This allows many different views of the same organ or structure, and provides much greater detail. The X-ray information is sent electronically to a computer, which interprets the X-ray data and displays it in a two-dimensional form on a monitor. The CT scan has become an important tool in medical imaging to supplement X-rays and medical ultrasonography. CT scanning of the head is typically used to detect, among other things, bleeding, brain injury, skull fractures, aneurysm, strokes, a blood clot or bleeding within the brain after a patient exhibits symptoms of an injury or other problem.

16. Under normal circumstances, a head CT scan is generally painless, non-invasive, and accurate. The effective radiation from a CT scan is usually about 1 to 2 millisievert (mSv), equivalent to the background radiation dose the average person receives over four to six months. The risk of developing a brain tumor or other cancer from this radiation exposure is generally not a major health concern.

17. However, increased levels of radiation exposure can also have negative consequences known as somatic effects. Somatic effects are, generally speaking, health risks for which the probability of a negative occurrence is considered to be a function of a dose of radiation above a threshold amount.

18. Somatic effects result from cells in the body being exposed to an amount of radiation which causes ionization of the chemical elements therein. This ionization either results in the immediate death of the cell or results in a change in the genetic code of the cells.

19. Fortunately, most chromosome changes are lethal to the affected cell. In some cases, however, they may cause abnormal growth patterns ultimately resulting in the formation of benign or cancerous tumors.

20. Hence, radiation is always damaging to the cells or tissue of the body. For this reason concentrated radiation doses are directed at cancer growth areas in the body – to kill or damage the cancerous tissue so that the growth and multiplication of the cancer is stopped.

21. As radiation can have both useful and detrimental effects, it was important to establish guidelines for those likely to encounter such exposure (e.g. healthcare workers, those undergoing CT scans, etc.). Guidelines have been established by the International Commission on Radiological Protection (the “ICRP”). The ICRP adopted the following principles for the use of radiation: 1) The application of radiation should be useful; and 2) The radiation dose should be as low as reasonably achievable (the “ALARA Principle”).

**The CT Machines  
Manufactured by GE Defendants**

22. The CT machines manufactured and sold by GE Defendants comprise a radiation-emitting technology that was researched, developed, designed, formulated, fabricated, tested, manufactured, produced, processed, assembled, inspected, marketed, labeled, promoted,

packaged, advertised for sale, sold or otherwise placed into the stream of commerce by the GE Defendants.

23. The GE Defendants knew and/or intended that the CT imaging equipment manufactured by the GE Defendants would be used in the treatment of a patient's condition, and specifically for the diagnosis of human illness, including the diagnosis of stroke or other brain-related disease, and that patients would be exposed to a small amount of radiation in the course of the radiological procedures.

24. On or about October 8, 2009, the U.S. Food and Drug Administration ("FDA") released a notification to healthcare professionals indicating that it had become aware of radiation overexposures during perfusion CT imaging performed to aid in the diagnosis of stroke. The FDA notice stated that, for an 18 month period, beginning in February, 2008, 206 patients had received radiation doses that were approximately eight times the expected level. Instead of receiving the expected dose of 0.5 Gray (abbreviated as "Gy") (maximum) to the head, these patients received 3-4 Gy. The FDA further indicated that "the magnitude of these overdoses and their impact on affected patients were significant."

25. The FDA further indicated that it had commenced a safety investigation, suggesting that the situation may reflect more widespread problems with CT quality assurance programs. A nationwide alert was issued by the FDA warning hospitals to check CT brain scan procedures. Huntsville Hospital received the warning. Hence, all Defendants knew or should have known of the risks of radiation overexposure which would result from using CT machines manufactured by the GE Defendants.

26. Due to the actions of GE Defendants in either the lack of including or maintaining appropriate safety functions, implementing confusing methodology, operating the machine

improperly or some other cause, the machines in question have emitted a much higher level of radiation than was either intended or is reasonably safe.

27. The radiation exposure which results is a proven hazardous substance inasmuch as same is a known carcinogen.

28. The exposure to a greater level of radiation than was intended results in a significantly-increased risk of contracting serious, latent diseases and other somatic effects.

29. The CT machines manufactured by the GE Defendants do not meet the guidelines established by the ICRP.

**Plaintiff Aletha H. Pardue's CT Scan Resulting in a  
Radiation Overexposure**

30. On or about December 9, 2008, Aletha H. Pardue received a CT scan of the head with and without contrast at Huntsville Hospital. The scan was performed by employees of Huntsville Hospital using equipment manufactured by the GE Defendants.

31. As a result of the scan, Ms. Pardue's hair immediately began to fall out (epilation) in a two-inch wide, band-like pattern. Much later, she suffered from other symptoms including impaired cognitive ability and/or deficiencies in short term memory, thyroid problems, skin spots, fatigue, dizziness, anemia, swelling of her hands and feet and unexplained weight loss. According to experts' present understanding, the genetic material of her brain cells was immediately damaged.

32. Either due to the lack of appropriate safety functions, faulty design, negligence, confusing methodology, recklessness, wantonness, some other cause, or a combination of the foregoing, Plaintiff was subjected to CT scans which emitted a much-higher level of radiation than was either intended or is reasonable to perform the diagnostic scan ordered.

33. The radiation to which Plaintiff was exposed is a proven hazardous substance inasmuch as same is a known carcinogen.

34. As a proximate result of the exposure to a greater level of radiation than was safe due to Defendants' negligence, recklessness, wantonness and/or other behavior, Plaintiff was immediately injured and now has a significantly-increased risk of contracting serious, latent diseases and/or other somatic effects.

### **CAUSE OF ACTION**

#### **Count I Breach of Express Warranty**

35. Plaintiff repeats and re-alleges paragraphs 1 through 34.

36. At all times mentioned herein, the GE Defendants expressly warranted to Plaintiff, and to her agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and/or in publications, package inserts, or other written materials intended for use by physicians, medical technicians, patients and the general public, that the aforementioned CT imaging machines were safe, effective, and proper for their intended use, throughout the course of that use by physicians, medical technicians, and patients.

37. In utilizing the aforementioned products, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the GE Defendants. Said warranties and representations were false in that the aforementioned CT imaging machines were not safe and were unfit for the use for which they were intended.

38. As a direct, proximate and legal result of the foregoing breach of express warranties by the GE Defendants, Plaintiff has incurred and will continue to incur medical, hospital and related expenses, pain and suffering and severe mental anguish.

39. As a further direct and proximate result of the acts and omissions of the GE Defendants, Plaintiff has sustained and will in the future sustain loss of earnings, loss of earning capacity, and other damages according to proof at the time of trial.

40. As a further direct and proximate result of the acts and omissions of the GE Defendants, Plaintiff has suffered and will continue to suffer severe and serious physical and emotional injuries resulting in damages in an amount to be ascertained according to proof at the time of trial.

41. Accordingly, Plaintiff seeks, and is entitled to, the relief requested against the GE Defendants.

**Count II**  
**Breach of Implied Warranty**

42. Plaintiff repeats and re-alleges paragraphs 1 through 41.

43. Prior to the time that the aforementioned CT imaging machines were utilized on Plaintiff, the GE Defendants impliedly warranted to Plaintiff and to her agents and physicians that said products were of merchantable quality and safe and fit for the use for which it was intended.

44. Plaintiff was and is unskilled in the research, design, and manufacture of CT imaging machines, and reasonably relied entirely on the skill, judgment, and implied warranty of the GE Defendants in researching, designing, manufacturing, marketing the products and training the purchaser of said products.

45. The CT imaging machines manufactured and sold by GE Defendants were neither safe for their intended use nor of merchantable quality as warranted by the GE Defendants in that they had dangerous propensities when put to their intended use and would cause serious injuries to the patient undergoing CT scans.



46. As a direct, proximate and legal result of the foregoing breach of implied warranties by the GE Defendants, Plaintiff has incurred and will continue to incur medical, hospital and related expenses, pain and suffering and severe mental anguish.

47. As a further direct and proximate result of the acts and omissions of the GE Defendants, Plaintiff has sustained and will in the future sustain loss of earnings, loss of earning capacity, and other damages according to proof at the time of trial.

48. As a further direct and proximate result of the acts and omissions of the GE Defendants, Plaintiff has suffered and will continue to suffer severe and serious physical and emotional injury resulting in damages in an amount to be ascertained according to proof at the time of trial.

49. Accordingly, Plaintiff seeks, and is entitled to, the relief requested against the GE Defendants.

#### **RELIEF REQUESTED**

WHEREFORE, Plaintiff prays that the Court:

1. Grant Plaintiff a jury trial of the issues in this case.
2. Declare that Defendants' equipment manufactured at issue breached both express and implied warranties.
3. Award compensatory damages to Plaintiff against GE Defendants for both past and future medical expenses, lost wages, pain and suffering and severe mental anguish, for a reasonable sum in excess of Seventy-five Thousand (\$75,000.00) Dollars, together with interest, costs and disbursements herein; and
4. Award such other, further and different relief, including equitable, that the Court deems just and proper.

Submitted this the 22<sup>nd</sup> day of April, 2011.

**PLAINTIFF DEMANDS TRIAL BY JURY**

s/Joel E. Smith

Mark R. Kosieradzki (ID #57745)

Joel E. Smith (ID #213184)

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